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November 4, 2005

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PATENT APPLICATION  
DOCKET NO.: 2316.2009-000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mary Jane Cardosa, Gerd Sutter and Volker Erfle  
Application No.: 10/786,380 Group Art Unit: 1642  
Filed: February 24, 2004 Examiner: Not Yet Assigned  
Confirmation No.: 3579

Title: Recombinant MVA Virus Expressing Dengue Virus Antigens and the Use Thereof in Vaccines

CERTIFICATE OF MAILING OR TRANSMISSION	
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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
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Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

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☐ a Statement under 37 CFR 1.97(e), as checked below, and  
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(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application file.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed (**B1-B10 and C1-C44**).
  - ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☒ The "concise explanation" requirement (non-English references) for references **B1, B4, C23, C24 and C34** under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☒ the enclosed/attached English language abstract.

[XX] Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_  
U.S. Patent Application No. 09/532,976, by Ingo Drexler, *et al.*, filed March 22, 2000, Docket No.: 2316.2001-000 (ABANDONED).

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- [X] A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- [ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: November 4, 2005

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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  November 4, 2005  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2316.2009-000		APPLICATION NO. 10/786,380	
	FIRST NAMED INVENTOR Mary Jane Cardosa		FILING DATE February 24, 2004	
	EXAMINER Not Yet Assigned		CONFIRMATION NO. 3579	GROUP 1642

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

C1	Altenburger, W., <i>et al.</i> , "Partial Deletion of the Human Host Range Gene in the Attenuated Vaccinia Virus MVA," <i>Arch. Virol.</i> , 105:15-27 (1989).
C2	Borsani, <i>et al.</i> , "Characterization of a Human and Murine Gene (CLCN3) Sharing Similarities to Voltage-Gated Chloride Channels and to a Yeast Integral Membrane Protein", <i>Genomics</i> 27:131-141 (1995).
C3	Bowie, <i>et al.</i> , "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", <i>Science</i> 257:1306-1310 (1990).
C4	Bray, M., <i>et al.</i> , "Mice Immunized with Recombinant Vaccinia Virus Expressing Dengue 4 Virus Structural Proteins With or Without Nonstructural Protein NS1 Are Protected Against Fatal Dengue Virus Encephaliti," <i>J. Virol.</i> 63(6):2853-2856 (1989).
C5	Cardosa, M.J., "Dengue vaccine design: issues and challenges," <i>British Medical Bulletin</i> , 54(2): 395-405 (1998).
C6	Carroll, M.W., <i>et al.</i> , "E. Coli $\beta$ -glucuronidase (GUS) as a marker for recombinant vaccinia viruses", <i>Biotechniques</i> , 19:352-355 (1995).
C7	Chakrabarti, <i>et al.</i> , "Vaccinia Virus Expression Vector: Coexpression of $\beta$ -Galactosidase Provides Visual Screening of Recombinant Virus Plaques," <i>Molecular and Cellular Biology</i> 5:3403-3409 (1985).
C8	Chambers, T.J., <i>et al.</i> , "Flavivirus Genome Organization, Expression, and Replication," <i>Annu. Rev. Micorobiol.</i> 44:649-688 (1990).
C9	Cruse, <i>et al.</i> , <i>Illustrated Dictionary of Immunology</i> , CRC Press, Boca Raton, pages 102-103 (1995).
C10	Deroo, S., <i>et al.</i> , "Antigenic and Immunogenic Phage Displayed Mimotopes as Substitute Antigens: Applications and Limitations," <i>Combinatorial Chemistry &amp; High Throughput Screening</i> 4:75-110 (2001).
C11	Eckels, <i>et al.</i> , "Immunization of Monkeys with Baculovirus-Dengue Type-4 Recombinants Containing Envelope and Nonstructural Proteins: Evidence of Priming and Partial Protection", <i>American Journal of Tropical Medicine and Hygiene</i> 50:472-478 (1994).
C12	Falconar, A.K.I., <i>et al.</i> , "Precise location of sequential dengue virus subcomplex and complex B cell epitopes on the nonstructural-1 glycoprotein," <i>Archives of Virology</i> , 137: 315-326(1994).

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C13	Falgout, <i>et al.</i> , "Immunization of Mice with Recombinant Vaccinia Virus Expressing Authentic Dengue Virus Nonstructural Protein NS1 Protects against Lethal Dengue Virus Encephalitis," <i>J. Virol.</i> 64:4356-4363 (1990).
C14	Fonseca, BA., et al., "Recombinant Vaccinia Viruses Co-Expressing Dengue-1 Glycoproteins PreM and E Induce Neutralizing Antibodies in Mice," <i>Vaccine</i> 12(3):279-285 (1994).
C15	Greenspan, <i>et al.</i> , "Defining Epitopes: It's not as easy as it seems," <i>Nature Biotechnology</i> 7:936-937 (1999).
C16	Gruenberg, <i>et al.</i> , "Partial Nucleotide Sequence and Deduced Amino Acid Sequence of the Structural Proteins of Dengue Virus Type 2, New Guinea C and PUO-218 Strains," <i>J. Gen. Virol.</i> 69:1391-1398 (1988).
C17	Hiramatsu, K., et al., "Mutational Analysis of a Neutralization Epitope on the Dengue Type 2 Virus (DEN2) Envelope Protein: Monoclonal Antibody Resistant DEN2/DEN4 Chimeras Exhibit Reduced Mouse Neurovirulence," <i>Virology</i> 224(2):437-445 (1996).
C18	Hirsch, V.M., <i>et al.</i> , "Limited Virus Replication Following SIV Challenge of Macaques Immunized with Attenuated MVA Vaccinia Expressing SIVsm env and gag-pol," <i>Vaccines 95, Cold Spring Harbor Laboratory Press, USA</i> , pgs. 195-200 (1995).
C19	Hirsch, V.M., <i>et al.</i> , "Patterns of Viral Replication Correlate with Outcome in Simian Immunodeficiency Virus (SIV)-Infected Macaques: Effect of Prior Immunization with a Trivalent SIV Vaccine in Modified Vaccinia Virus Ankara," <i>J. Virol.</i> , 70(6):3741-3752 (1996).
C20	Henchal, E.A., <i>et al.</i> , "Synergistic Interactions of Anti-NS1 Monoclonal Antibodies Protect Passively Immunized Mice from Lethal Challenge with Dengue 2 Virus," <i>J. Gen. Virol.</i> 69:2102-2107 (1988).
C21	Jianmin, Z., et al., "Analysis of Functional Epitopes on the Dengue 2 Envelope (E) Protein Using Monoclonal IgM Antibodies," <i>Arch Virol.</i> 140(5):899-913 (1995).
C22	Mackett, <i>et al.</i> , "General Method for Production and Selection of Infectious Vaccinia Virus Recombinants Expressing Foreign Genes," <i>J. Virol.</i> 49:857-864 (1984).
C23	Mayr, A., <i>et al.</i> , "The Smallpox Vaccination Strain MVA: Marker, Genetic Structure, Experience Gained with the Parenteral Vaccination and Behavior in Organisms with a Debilitated Defence Mechanism," <i>Zbl. Bakt. Hyg., I Abt. Org. B</i> , 167:375-390 (1978).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
C24	Mayr, A., <i>et al.</i> , "Abstammung, Eigenschaften und Verwendung des Attenuierten Vaccinia-Stammes MVA," <i>Infection</i> , 3:6-14 (1975).
C25	Megret, <i>et al.</i> , "Use of Recombinant Fusion Proteins and Monoclonal Antibodies to Define Linear and Discontinuous Antigenic Sites on the Dengue Virus Envelope Glycoprotein", <i>Virology</i> 187:480-491 (1992).
C26	Meyer, H., <i>et al.</i> , "Mapping of Deletions in the Genome of the Highly Attenuated Vaccinia Virus MVA and their Influence on Virulence," <i>J. Gen. Virol.</i> , 72:1031-1038 (1991).
C27	Moss, B., <i>et al.</i> , "New mammalian expression vectors," <i>Nature</i> 348(6296): 91-92 (1990).
C28	NTIS Accession Number PB, 88201363, "Novel Recombinant Vaccinia Virus Expression Vectors and Method of Selecting Same".
C29	NTIS Accession Number PB89144802, "Novel Inhibitor of HIV Infection".
C30	NTIS Accession Number PB88192059, " A Synthetic Antigen Evoking Anti-HIV Response".
C31	Pupo-Antunez, Maritza <i>et al.</i> , "Monoclonal Antibodies Raised to the Dengue-2 Virus (Cuban: A15 Strain) Which Recognize Viral Structural Proteins," <i>Hybridoma</i> , 16(4): 347-353 (1997).
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C33	Smucny, JJ., <i>et al.</i> , "Murine Immunoglobulin G Subclass Responses Following Immunization With Live Dengue Virus or a Recombinant Dengue Envelope Protein," <i>Am J. Trop Med. Hyg.</i> 53(4):432-437 (1995).
C34	Stickl, H., <i>et al.</i> , "MVA-Stufenimpfung Gegen Pocken" <i>Dtsch. Med. Wschr.</i> , 99:2386-2392 (1974).
C35	Sutter, G., <i>et al.</i> , "A Recombinant Vector Derived from the Host Range-Restricted and Highly Attenuated MVA Strain of Vaccinia Virus Stimulates Protective Immunity in Mice to Influenza Virus," <i>Vaccine</i> , 12(11):1032-1040 (1994).
C36	Sutter, G. and Moss, B., "Nonreplicating Vaccinia Vector Efficiently Expresses Recombinant Genes," <i>Proc. Natl. Acad. Sci., USA</i> , 89:10847-10851 (1992).

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C37	Sutter, G., et al., "Non-Replicating Vaccinia Vector Efficiently Expresses Bacteriophage T7 RNA Polymerase," <i>FEBS Letters</i> 371:9-12 (1995).	
C38	Sutter, G. and Moss, B., "Novel Vaccinia Vector Derived from the Host Range Restricted and Highly Attenuated MVA Strain of Vaccinia Virus," <i>Dev. Biol. Stand. Basel, Karger</i> , 84:195-200 (1995).	
C39	Srivastava, <i>et al.</i> , "Mice Immunized with a Dengue Type 2 Virus E and NS1 Fusion Protein Made in <i>Escherichia coli</i> are Protected Against Lethal Dengue Virus Infection," <i>Vaccine</i> 13:1251 (1995).	
C40	Venugopal, K., <i>et al.</i> , "Towards a New Generation of Flavivirus Vaccines," <i>Vaccine</i> 12:11-20 (1994).	
C41	Wang, S., et al., "Antibody-Enhanced Binding of Dengue-2 Virus to Human Platelets," <i>Virology</i> 213(1):254-257 (1995).	
C42	Wyatt, <i>et al.</i> , "Replication-deficient vaccinia virus encoding bacteriophage T7 RNA polymerase for transient gene expression in mammalian cells", <i>Virol.</i> , 210:202-205 (1995).	
C43	Zhao, <i>et al.</i> , "Cloning Full-Length Dengue Type 4 Viral DNA Sequences: Analysis of Gene Coding for Structural Proteins," <i>Virology</i> 155:77-88 (1986).	
C44	Zhao, <i>et al.</i> , "Expression of Dengue Virus Structural Proteins and Nonstructural Protein NS <sub>1</sub> by a Recombinant Vaccinia Virus," <i>J. Virol.</i> 61:4019-4022 (1987).	

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